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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/934,367	09/19/97	NEEDLEMAN	P MON-103.0-(6

HM12/1023

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EXAMINER	
DAVIS, M	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/934,367	NEEDDLEMAN ET AL
Examiner	**Art Unit**
MINH TAM DAVIS	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 7, 2001* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-11 and 15-31* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-11 and 15-31* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1-11, 15-31are being examined.

The following are the remaining rejections.

DOUBLE PATENTING

Applicant asserts that a provisional terminal disclaimer will be filed upon a finding that the present application is otherwise in condition for allowance, should those applications still be pending with claims requiring disclaimer.

The rejection will stay in hold until the present application is in condition for allowance, if the claims are allowable.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 22 and 23 are indefinite, because it is not clear in claims 22 and 23, what is meant by "polypeptides are each independently of a sequence"..

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, ENABLEMENT

Rejection under 35 USC 112, first paragraph of claims 2-3, 5-11, 15-16, 23-27 pertaining to lack of enablement for a process of increasing the concentration of HDL cholesterol in blood of a mammal, remains for reasons already of record in paper No.18.

Applicant argues that Table 1 represents a comparison of pre-immune sera and first-immune sera. Table 1 illustrates that even after a single inoculation, a measurable increase occur in HDL level. The claims are unrelated to table 1, and are drawn to repeated immunization. Applicant recites *In re Brana, In re Marzocchi, and In re Eltgroth*, stating that the PTO cannot make this rejection unless it has reason to doubt the objective truth of the statements in the written description. The Examiner has not presented evidence to refute the enablement of repeatly immunizing a mammal with an inoculum containing CETP immunogen, until the HDL cholesterol in the blood is increased to about 10 percent relative to the HDL cholesterol value prior to a first immunization.

Applicant's arguments set forth in paper No.21 have been considered but are not deemed to be persuasive for the following reasons:

The recitation of the case law *In re Brana, In re Marzocchi, and In re Eltgroth* is acknowledged.

The specification discloses in table 1 that the p value for HDL level after injection of recombinant human CETP or C-terminal rabbit CETP amino acids conjugated to an antigenic carrier, thyroglobulin, is 0.17 and 0.38, respectively, as compared to the control. It is well known

in the art that a p value from a Student's T test should be less than or equal to 0.05 to be significant. In other words, the 10 percent difference seen in table 1 is due to variation within samples, rather than a significant difference in HDL between the control and the animals immunized with recombinant human CETP, or with C-terminal rabbit CETP conjugated to thyroglobulin. Since there is no significant increase in HDL cholesterol after the first injection of the CETP immunogen, as shown in table 1, it is unpredictable that further repeated injections would result in a significant increase in HDL cholesterol in treated subjects.

17-27, 29-31

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Rejection under 35 USC 112, first paragraph of claims 1-11, ~~15~~-16, ~~23~~ 22-27 pertaining to lack of enablement for a process of increasing the concentration of HDL cholesterol in blood of a mammal, remains for reasons already of record in paper No.18. Should be 17-21, 29-31

Applicant argues that the specification gives operative examples of sequences known to be both antigenic and antagonistic to CETP. In order to fall within the scope of claims 1-11, and 16-31, as amended, the CETP immunogen must both raise antibodies and increase HDL-cholesterol. Because those skilled in the art would appreciate that certain CETP amino acid residue sequences raised antibodies and are antagonistic with respect to CETP biological activity, Applicant is entitled to the full scope of these claims.

Applicant's arguments set forth in paper No.21 have been considered but are not deemed to be persuasive for the following reasons:

It is noted although claim 1 is broadly drawn to a process for producing antibodies to CETP, the specification clearly intends to raise antibodies that are antagonistic to CETP, wherein only antibodies that are antagonistic to CETP could increase HDL-cholesterol via inhibition of the activity of CETP. Thus claim 1 encompasses a process for producing antibodies that are antagonistic to CETP, comprising immunizing a mammal with any 10 to 30 residues of an immunogenic sequence of CETP.

Rejection remains, because not any fragment of a protein is involved in its activity, and it is unpredictable that any 10 to 30 residues of an immunogenic sequence of CETP, or SEQ ID Nos: 2, 3, 6-9, 11-13, 32-33, 35-37 are in a region that is involved in the biological activity of CETP, such that antibodies specific for these claimed sequences would inhibit the biological activity of CETP. Further, it is unpredictable whether the claimed sequences are exposed on the surface of CETP such that antibodies against these claimed sequences could bind to CETP via the claimed sequences.

REJECTION UNDER 35 USC 102(b)

Rejection under 35 USC 102(b) claim 29 pertaining to anticipation by Jeong et al, remains for reasons already of record in paper No.18.

Applicant asserts that claim 29 has been amended to include a limitation of a "CETP amino acid residue sequence of about 10 to 30 residues". Jeong does not teach a CETP amino acid residue sequence of about 10 to 30 residues.

Applicant's arguments set forth in paper No.21 have been considered but are not deemed to be persuasive for the following reasons:

A CETP amino acid residue sequence of "about 10 to 30 residues" still reads on the 31 amino acid sequence taught by Jeong et al.

REJECTION UNDER 35 USC 103

1. Rejection under 35 USC 103 claims 29, 30 pertaining to obviousness by Jeong et al, in view of PN=5,650,298 remains for reasons already of record in paper No.18.

Applicant asserts that claim 29 has been amended to include a limitation of a "CETP amino acid residue sequence of about 10 to 30 residues". Jeong does not teach a CETP amino acid residue sequence of about 10 to 30 residues. Applicant further asserts that the secondary reference does not suggest combining with or modifying Jeong in such as way as to make claims 29 and 30 obvious.

Applicant's arguments set forth in paper No.21 have been considered but are not deemed to be persuasive for the following reasons:

A CETP amino acid residue sequence of "about 10 to 30 residues" of claim 29 still reads on the 31 amino acid sequence taught by Jeong et al.

Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is

what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus, it would have been obvious to replace the promoter taught by Jeong et al with any other promoter, because they all would produce the claimed protein.

2. Rejection under 35 USC 103 claims 1, 2, and 22 pertaining to obviousness by Jeong et al, in view of Felgner et al, further in view of Silversides et al remains for reasons already of record in paper No.18.

Rejection remains because Applicant has not answered to the rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wesnesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

October 11, 2001

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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